Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Draft Guidance for Industry and FDA

Draft Guidance – Not for Implementation

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Dental Branch
Division of Dental, Infection Control, and General Hospital Devices
Office of Device Evaluation

Preface

Public Comment:

For 90 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions regarding this draft document should be submitted to Docket No. [*CDRH OSM will add on posting*], Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852.

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Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Draft Guidance for Industry and FDA

This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

1. Background

This draft guidance document was developed as a special control guidance to support the classification of the intraoral devices for snoring and/or obstructive sleep apnea into class II. Intraoral devices for snoring and obstructive sleep apnea are preamendments devices, i.e., were in commercial distribution prior to May 28, 1976 (the enactment date of the Medical Device Amendments of 1976) and are currently unclassified. The Dental Devices Panel met to consider the classification of these devices in November 1997. The Panel recommended these products be classified into Class II (special controls). The device, as proposed, is intended for use during sleep to aid in the treatment of simple snoring and/or obstructive sleep apnea.

This draft guidance will be issued in conjunction with a Federal Register notice announcing the proposal to classify this device type. This guidance is issued for comment purposes only. If a final rule to classify this device type is not issued, this guidance document will not be issued as a special control.

FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of intraoral devices for snoring and/or obstructive sleep apnea. Thus, a manufacturer who intends to market a device of this generic type should (1) conform with the general controls of the Federal Food, Drug & Cosmetic Act (the Act), including the 510(k) requirements described in 21 CFR 807 Subpart E, (2) address the specific risks to health associated with intraoral devices for snoring and/or obstructive sleep apnea, and unless exempt from the premarket notification requirements of the Act, (3) receive a substantial equivalence determination from FDA prior to marketing the device.

This special control guidance document identifies the classification, product code, and classification identification for the intraoral devices for snoring and/or obstructive sleep apnea. In addition, it lists the risks to health identified by FDA and serves as the special control that, when followed and combined with the general controls, will generally

address the risks associated with this generic device type and lead to a timely 510(k) review and clearance. For the specific content requirements of a 510(k) submission, you should refer to 21 CFR 807.87 and other agency documents on this topic, such as "510(k) Manual - Premarket Notification: 510(k) - Regulatory Requirements for Medical Devices," http://www.fda.gov/cdrh/manual/510kprt1.html.

Device manufacturers may submit an Abbreviated 510(k) when: (1) a guidance documents exists, (2) a special control has been established, or (3) FDA has recognized a relevant consensus standard. FDA believes an Abbreviated 510(k) is the least burdensome means of demonstrating substantial equivalence once a Class II Special Controls Guidance Document has been issued. See also **The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance**, http://www.fda.gov/cdrh/ode/parad510.html.

An Abbreviated 510(k) submission should include the required elements identified in 21 CFR 807.87, including a description of the device, the intended use of the device, and the proposed labeling for the device. An Abbreviated 510(k) should also include a summary report. In an Abbreviated 510(k), FDA may consider the contents of a summary report to be appropriate supporting data within the meaning of 21 CFR 807.87(f) or (g).

The summary report should briefly describe the methods or tests used and the acceptance criteria applied to address the risks identified in this guidance document as well as any additional risks specific to your device. When a suggested test method is followed, a simple reference to the method will be an acceptable description. If there are any deviations from a suggested test method, you should provide more detailed information in the summary report to characterize the particular deviation. The summary report should also either (1) briefly present summary results of each test in tabular form **or** (2) describe the acceptance criteria to be applied to the test results. (See also 21 CFR 820.30 Subpart C Design Controls for the Quality System Regulation.)

2. Scope

The scope of this document is limited to the generic type of device described below.

21 CFR 872.5570 Intraoral devices for snoring and/or obstructive sleep apnea.

Product codes: LRK Anti-Snoring Device
LQZ Jaw Repositioning Device

This generic type of device includes intraoral devices for snoring and/or obstructive sleep apnea. These are removable medical devices that are fitted in the patient's mouth and are indicated to treat patients who snore and patients who have obstructive sleep apnea. The devices are indicated to be used when the diagnosis is simple snoring or obstructive sleep apnea. The devices are indicated for use during sleep to aid in the treatment of these conditions. Simple snoring is a form of sleep disordered breathing in which there is a narrowing of the upper airway which leads to an inspiratory noise produced by vibration

of the pharyngeal soft tissues. These devices are not indicated for the treatment of central apnea. Intraoral devices to treat snoring and/or obstructive sleep apnea are prescription devices unless adequate directions for use (21 CFR 801.5) are developed and FDA clears a 510(k) specifically for over-the-counter (OTC) distribution.

Intraoral devices to treat snoring and/or obstructive sleep apnea include three basic designs: mandibular repositioners, tongue retaining devices, and palatal lifting devices. All of these devices provide the same therapeutic goal of increasing the pharyngeal space to improve the patient's ability to exchange air. The increase in airway space decreases the air turbulence, which is a causative factor in snoring.

In addition to the removable devices, there are implantable screw devices that may be used with a suturing technique as part of a surgical procedure to lift the intraoral musculature and provide improved oropharyngeal patency (airway space). **Implantable screw devices are not included in this classification**.

3. Risks to Health

FDA has identified the risks to health generally associated with the use of intraoral devices for snoring and/or obstructive sleep apnea in the table below. You should also conduct a risk analysis, prior to submitting your 510(k), to identify any other risks specific to your device. The premarket notification should describe the risk analysis method. The measures recommended to mitigate the identified risks are given in this guidance document, as shown in the table below. (If a manufacturer elects to use an alternative approach to address a particular risk, or has identified risks additional to those in the guidance, you should provide sufficient detail to support the alternative approach.)

Identified risk	Recommended mitigation measures
Intraoral gingival, palatal, or dental soreness	Sections 6, 7, 8, 9
Temporomandibular Joint (TMJ) Dysfunction Syndrome	Section 8, 9
Obstruction of oral breathing	Sections 8, 9
Loosening or flaring of lower anterior teeth or general tooth movement	Sections 8, 9

4. Controls

FDA believes that the measures in the following sections of this guidance, when combined with general controls, will address the identified risks to health associated with the use of the intraoral devices for snoring and/or obstructive sleep apnea. You should demonstrate that your device complies with either the specific recommendations of this guidance or an alternate means to address the above identified risks, in order to

provide reasonable assurance of the safety and effectiveness of the device. If you have identified any additional risks, specific to your device, your 510(k) should identify those risks, as well as the methods or tests used and the acceptance criteria applied to address them.

5. Abbreviated 510(k) Content

An Abbreviated 510(k) that relies on a Class II Special Controls Guidance Document should contain the following.

Coversheet

The coversheet should prominently identify the submission as an Abbreviated 510(k) and cite the title of the specific Class II Special Controls Guidance Document.

Items Required Under 21 CFR 807.87

The items required under 21 CFR 807.87 are:

- **Description of the device and its intended use.** The description should include a compete discussion of the performance specifications and, when appropriate, detailed, labeled drawings of the device You should also submit an "indications for use" enclosure. See http://www.fda.gov/cdrh/ode/indicate.html for the recommended format.

- **Proposed labeling.**

- **Summary report.** A summary report should describe how the Class II Special Controls Guidance Document was used to address the risks associated with the particular device type. The summary report should contain:

  - Risk analysis.

  - Description of device performance requirements.

  - Discussion of the features and functions provided to address the risks identified in this Class II Special Controls Guidance Document, as well as any additional risks identified in your risk analysis.

  - For each performance aspect identified in sections 6-9 of this Class II Special Controls Guidance document, you should briefly discuss each test method and identify your acceptance criteria. When a suggested test method is followed, a simple reference to the method will be an acceptable description. If there are any deviations from a suggested test method, you should provide more detailed information in the summary report to characterize the particular deviation. The summary report should also either (1) briefly present the data resulting from

each test in tabular form **or** (2) describe the acceptance criteria to be applied to the test results. If any test article does not meet the identified acceptance criteria, you may not market your device. Instead, you must submit a new 510(k) with revised acceptance criteria, 21 CFR 807.81(a)(3). The new 510(k) must be cleared by FDA before you market your device. (21 USC 513(i)(1)(A).

- If any part of the device design or testing relies on a recognized standard, the summary report should include: (1) a statement that testing will be conducted and meet specified acceptance criteria before the product is marketed, or (2) a declaration of conformity to the standard. Testing must be completed before submitting a declaration of conformity to a recognized standard. (21 USC 514(c)(2)(B)). For more information, see FDA guidance, **Use of Standards in Substantial Equivalence Determinations; Final Guidance for Industry and FDA**, http://www.fda.gov/cdrh/ode/guidance/1131.html.

- If FDA recommends a clinical study for your device (see section 8), your summary report should describe your clinical protocol and include all the information described in section 8. If you have omitted any of this information, you should explain, in your summary report, how substantial equivalence can be determined without it.

If it is not clear how you have addressed the risks identified by FDA or by your risk analysis, we may request additional information about aspects of the device's performance characteristics. We may also request additional information, if we need it to assess the adequacy of your acceptance criteria.

As an alternative to submitting an Abbreviated 510(k), you can submit a traditional 510(k) that provides all of the information and data described in this guidance. A traditional 510(k) should include all of your methods, data, acceptance criteria, and conclusions.

6. Material Composition

Your summary report should include the following information for all components.

- The material identity
- The complete chemical composition, unless declaring conformance to a materials standard
- Material safety data sheets (MSDS) for all materials used in the device (appended to your summary report).

7. Biocompatibility

You should perform biocompatibility testing as outlined in the FDA-modified "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing" http://www.fda.gov/cdrh/g951.html for a surface device that contacts intraoral (i.e., mucosal, gingival, and palatal) surfaces for prolonged contact. Your summary report should contain either a statement that testing will be conducted as described in the standard (the statement should also include the acceptance criteria to be applied) or declaration of conformity to Parts 5 and 10 of ISO-10993.

8. Clinical Testing

In accordance with the Least Burdensome provisions of the FDA Modernization Act of 1997, the agency will not request clinical studies for new devices unless there is a specific justification for asking for such information to support a substantially equivalent determination. FDA recommends that you conduct clinical studies for intraoral devices for snoring and/or obstructive sleep apnea when your device:

- uses designs dissimilar from designs previously cleared under a 510(k) [Please note: Devices that use the same mechanism of action are not necessarily similar devices.]
- uses new technology, i.e., technology different from that used in legally marketed intraoral devices for snoring and/or obstructive sleep apnea
- makes changes in the indication for use.

The summary report should include the clinical protocol defining inclusion and exclusion criteria and a sample size justification.

For devices for simple snoring, performance measurements should include the rate of reduction of snoring based on clinical observation.

For devices for obstructive sleep apnea, performance measurements should include the rate of reduction of apneic events measured by polysomnograms. Baseline and post-insertion polysomnograms should be obtained for each subject in the study. These polysonograms should include measurements of the respiratory disturbance index, apnea index, duration of the apnea, and oxygen saturation. FDA believes that polysomnographic data are needed for the intended use of obstructive sleep apnea.

Clinical studies to support a substantially equivalent determination for a non-prescription intraoral device for simple snoring also need to demonstrate that the instructions for use are adequate to provide a reasonable assurance of safety and effectiveness under the conditions of use. We suggest that you discuss your proposed protocol with the Division of Dental, Infection Control, and General Hospital Devices before initiating a clinical study of this kind.

9. Labeling

The premarket notification must include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e).

Intraoral devices for snoring and/or obstructive sleep apnea are prescription medical devices unless FDA determines that adequate directions for safe lay use have been developed. Final labeling for medical devices must comply with the requirements of 21 CFR 801.1 and final labeling for prescription medical devices must comply with 21 CFR 801.109 before being introduced into interstate commerce.

The following information is aimed at assisting manufacturers in complying with 801.109.

Prescription Device

In accordance with 21 CFR 801.109, prescription intraoral devices for snoring and/or obstructive sleep apnea must bear the following caution statement: "Caution: Federal law restricts this device to sale by or on the order of a physician."

Devices with Thermal Setting Resins

If the device contains a thermal setting resin, you should include instructions for heating, cooling, and setting time in the labeling.

Contraindications

You should include the following contraindications in your labeling. The device is contraindicated for patients who:

- have central sleep apnea
- have severe respiratory disorders
- have loose teeth or advanced periodontal disease
- are under 18 years of age.

Warnings

You should include the following warnings in your labeling. Use of the device may cause:

- tooth movement or changes in dental occlusion
- gingival or dental soreness
- pain or soreness to the temporomandibular joint
- obstruction of oral breathing
- excessive salivation.

Precautions

You should include the following precaution: Dentists should consider the medical history of the patients, including history of asthma, breathing, or respiratory disorders, or other relevant health problems, and refer the patient to the appropriate healthcare provider before prescribing the device.

Patient Labeling

Patient labeling should be clear, accurate, and provide complete use and care instructions for the patient. Information on patient labeling is available in the guidance entitled, "Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers," issued April 19, 2001, http://www.fda.gov/cdrh/ohip/guidance/1128.html.

10. Investigational Device Exemptions

Clinical design validation studies conducted after FDA determines that the device is substantially equivalent are exempt from investigational device exemptions (IDE) requirements in accordance with 21 CFR 812.2(c)(2). However, such studies must be performed in conformance with 21 CFR parts 50 and 56.

If a clinical study is needed to demonstrate substantial equivalence, i.e., conducted prior to obtaining 510(k) clearance of the device, the study must be conducted under the IDE regulation (21 CFR 812). FDA has determined that these devices are non-significant risk, and therefore studies of this device are subject only to the abbreviated requirements of 21 CFR 812.2(b).